

## DEPARTMENT OF HEALTH PROFESSIONS - DIRECTIVES

**DIRECTIVE NO.:** 4.5

**EFFECTIVE:** \_\_\_\_\_

**SUPERSEDES:** \_\_\_\_\_

**APPROVAL:** \_\_\_\_\_

### **4.5 Tampering Threat Procedures**

**Purpose:** The purpose of this directive is to assure appropriate response to tampering, misbranding, and adulteration of products or other like occurrences.

**Policy:** The Department will investigate all reports of suspected tampering associated with products regulated by the boards within the Department to the extent it has jurisdiction, including embargo of products and, where appropriate, refer such reports to agencies having capability and jurisdiction to provide public protection.

#### **Procedure:**

##### **I. Initial Receipt of Tampering Information:**

Upon receipt of information of tampering, the employee receiving such information shall:

- A. Attempt to obtain the following information, using, if possible, the "Initial Tampering Report Form" (see Appendix I).

NOTE: Do not anticipate answers to all questions: however, some people are extremely excitable and may inadvertently respond.

1. Exact words used by person making tampering threat or providing tampering information;
2. Exact time threat was received;
3. Date threat was received;
4. Exact name of product involved;
5. Type of container and package size; e.g. a glass bottle containing 100 tablets, capsules.
6. Number of units involved in tampering; e.g., Ten bottles of 100s; Two bottles of 50s.

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7. Method used to tamper product;
  8. Substance used to tamper product;
  9. Identification of tampered product;
  10. Location of tampered product; e.g., store, name, and location.
  11. Date tampered product placed at location.
  12. Person providing information (title, name, address, location, male, or female).
  13. If telephone call, the number from where the call came.
  14. Any background noise heard during the call; e.g., traffic, music, construction, chimes, etc.
- B.** Upon completing the received information, the employee receiving the information should immediately:
1. Complete the "Initial Tampering Threat Report Form";
  2. Hand deliver the report to the Director; if not available, to the person listed No. 2 on the Department's call list, or, if not available; continue numerically down the contact list, beginning with the person listed as No. 3 (see Appendix II);
  3. Notify their supervisor of receiving tampering information; and
  4. Provide the supervisor with a copy of the completed "Initial Tampering Threat Report Form."

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**II. Director's Responsibility:**

- A.** Upon receipt of an "Initial Tampering Threat Report Form," the Director, or, in his absence, his designee, will:
- 1.** Review the report with the person submitting it to determine:
    - a.** Nature and extent of problem;
    - b.** Jurisdiction;
    - c.** If additional information necessary; and
    - d.** Appropriate course of action.
  - 2.** Contact the person providing the tampering information, if necessary, for additional or clarification of information.
- B.** Upon completion and review of the report, the Director, or, in his absence, his designee, will contact the following:
- 1.** Secretary of Human Resources and advise:
    - a.** A tampering threat has been received;
    - b.** Nature and extent of tampering;
    - c.** Course of action.
  - 2.** The Administrator and the President of the Board of Pharmacy and advise:
    - a.** A tampering threat has been received.
    - b.** Nature and extent of threat; and
    - c.** Provide the tampering report and action taken to that point in order for the Board to initiate an action plan.

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C. The Director, or in his absence, his designee, will contact the following agencies, where appropriate:

1. Federal Food and Drug Administration.

FDA is authorized to investigate reported tampering of FDA regulated products, such as drugs, medical devices, cosmetics, foods, and animal feeds. Investigation could consist of inspections, sample collection, interviews, and affidavits. Assistance will be provided as necessary or where requested. FDA actions could include ordering a recall of the suspected product, seizure of product, and/or seeking an injunction to prevent distribution and sale of a product.

a. Upon receipt of a tampering report, advise FDA of the following:

1. A tampering report has been received;
2. Nature and extent of tampering as known;
3. Planned course of action; and
4. May need assistance, if required, for laboratory examination of tampered products and technical guidance.

b. FDA telephone numbers are:

Business Hours:

Baltimore District	(410) 962-2357*
Richmond Field Office	(804) 379-1627
Norfolk Field Office	(804) 441-3326 or 3327
Roanoke Field Office	(540) 265-6037 or 6040

\*If no answer in the Richmond, Norfolk, or Roanoke Field Office, contact the Baltimore District Office.

After Hours:

Baltimore District	(410) 962-3396
Washington Headquarters	(703) 285-2578
	(410) 443-4667

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2. Virginia Department of Health:

The Health Department has no jurisdiction on drugs, but it does have general power to protect the public. Usually, toxic substances are used to tamper products. Health Department actions could include invoking emergency powers to close down a contaminated water supply or restaurant processing contaminated food.

a. If the tampering caused an illness or the substance used to tamper the product is identified, advise the Health Department of the following:

1. A tampering report has been received;
2. Nature and extent of tampering as known;
3. Planned course of action;
4. Substance used to tamper product; and
5. May need to provide information on substance used to tamper product.

b. Department of Health telephone numbers are:

Contact Officer:	Dr. Carl Armstrong, Director Health Hazard Control
Work:	(804) 786-6029
Home:	(804) 744-3268

Back-Up Contact:	Dr. Gerald Llewellyn, Director Toxic Substance Information
Work:	(804) 786-1763
Home:	(804) 747-0756

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**3. Division of Forensic Science:**

Division of Forensic Science can provide laboratory examination of suspected tampered products.

**a.** If laboratory examination of products is required, advise Forensic Science of the following:

- 1.** A tampering report has been received;
- 2.** Nature and extent of the tampering as known and the suspected or reported substance (chemical or microbiological) used in tampering incident(s);
- 3.** May need assistance in performing laboratory examination of the tampered product.

**b.** Forensic Science telephone numbers are:

Contact Officer: Dr. Paul B. Ferrara, Division Director  
Work: (804) 786-2281  
Home: (804) 748-3684

Back-Up Contact: Robin Porter, Deputy Director  
Work: (804) 786-2281  
Home: (804) 744-7532

**4. Department of State Police Bureau of Criminal Investigation:**

The Department of State Police has jurisdiction over criminal investigation. State Police actions could include investigation and arrest.

**a.** If criminal acts are involved, advise State Police of the following:

- 1.** A tampering report has been received;
- 2.** Criminal acts are involved; and
- 3.** May request assistance in conducting criminal investigation.

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**b.** State Police telephone number is:

**5. Attorney General's Office:**

The Attorney General's Office will provide legal consultation and assistance in determining jurisdiction. The Attorney General's actions could include seeking injunctions and embargo orders.

**a.** If legal consultation, such as jurisdiction, is required, advise the Attorney General's Office of the following.

- 1.** A tampering report has been received;
- 2.** The nature and extent of the tampering as known; and
- 3.** May need legal assistance in determining jurisdiction, and seizure authority.

**b.** Attorney General's telephone number is as follows:

Contact Person:	Howard M. Casway
Work	(804) 786-1023
Home:	(804) 741-6188

**6.** The Department of Agriculture and Consumer Services has two divisions which could have jurisdiction in a tampering incident. The divisions are:

**a.** Product and Industry Regulation Division

Product and Industry Regulation Division has jurisdiction over medicated feeds and animal remedies. An animal remedy is a drug product used to treat animals which can be purchased without a prescription. Each medicated feed and remedy must be registered.

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1. If tampering involves a medicated feed or an animal remedy, advise the Product and Industry Regulation Division of the following.
  - a. A tampering report has been received;
  - b. Nature and extent of tampering as known; and
  - c. Would provide assistance, if requested.
2. Product and Industry Regulation Division phone number is as follows:

Contact Officer: N.K. Cooke, Supervisor  
Work: (804) 786-3514  
Home: (804) 675-0199

- b. Dairy and Food Division:

Dairy and Food Division has jurisdiction over unprocessed and processed dairy products and food products. Some of the dairy products included in this coverage are raw milk, ice cream, frozen desserts and similar products, and various other manufactured milk products such as hard and soft cheeses and products that include various milk ingredients. The Department of Agriculture and Consumer Services' actions could include seizure of suspected products and a "stop sale and use" order. 1. If tampering involves a dairy or food product, advise the Dairy and Food Division of the following:

- a. A tampering report has been received;
- b. Nature and extent of tampering as known; and
- c. Would provide assistance, if requested.

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2. Dairy and Food Division telephone number is as follows:



Contact officer: A.D. Dell Aria  
Chief of Food Inspection  
Work: (804) 786-3520  
Home: (804) 275-5669

Contact Officer: John Beers  
Chief, Bureau of Dairy Services  
Work: (804) 786-1452  
Home: (804) 353-6263

#### IV. Investigations:

Upon receipt of the information involving tampering from the Director, the Enforcement Division will immediately commence an investigation. Unless otherwise directed, such investigation will take priority over all other activities.

Tampering incidents have occurred in unpredictable forms and products; therefore, specific guidance on conducting investigations is not appropriate. Standard investigative protocols as outlined in the Investigator's Manual will suffice in most cases for these investigations. As events take place, specific instructions for some investigations may be provided by the Department.

##### A. General Procedures:

1. The Investigator assigned to the case should attempt to answer the following questions as rapidly as possible.
  - a. Has tampering occurred, or can the condition of the product be explained by other means?
  - b. Is death, injury, or illness associated with the report? If so, does it appear to be caused by the product defect?

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- c. Does the incident appear to be isolated or widespread?
- d. If not isolated, could the product defect occur at the production facility or in the distribution chain?
- e. Can specific persons or points in the distribution chain be identified as

possibly causing the problem?

2. If the investigation indicates that tampering has occurred, the investigator should:
  - a. Determine if the tampering occurred at the manufacturer, wholesaler, or retailer level, or while in the possession of the consumer.
  - b. Assure that suspect products are removed from distribution or sale.
  - c. Ensure that a chain of custody is maintained and documented for suspect products upon receipt of it or any subsequent transfers.
  - d. Identify the person(s) responsible for the incident.

**B. Department Contact:**

The Director of Enforcement would be the focal point for coordinating and being the communication officer for the investigation, especially in isolated tampering cases.

**C. Task Force:**

Should the tampering incident require the formation of a task force, the Director shall:

- a. Designate the role and membership of the task force.
- b. Direct such a request to the Secretary of Human Resources suggesting agencies to be represented.

**D. Investigative Report:**

Upon completion of any investigation, a fully developed report must be submitted to the Director.

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**V. POLICY LOCATION:**

This policy will be maintained at each work station in the Department and be readily accessible to all employees.

**INITIAL TAMPERING THREAT REPORT FORM**

- 1. Exact words by person making tampering threat or providing tampering information.  
(Use additional paper, if necessary.)**
  
- 2. Exact time threat was received:**
- 3. Date threat was received:**
- 4. Exact name of product involved:**
- 5. Type of container and package size:**
- 6. (e.g. A Glass bottle containing 100 tablets, capsules.)**

6. **Number of units involved in tampering:**  
(e.g. 10 bottles of 100's, 2 bottles of 50's.)
7. **Method used to tamper product:**
8. **Substance used to tamper product:**
9. **Identification of tampered product:**  
(e.g. How can the product be identified.)
10. **Location of tampered product: (e.g. store, name, and location)**
11. **Date tampered product placed at location:**
12. **Person providing tampering information:**
- Title:**
- Name:**
- Address:**
- Location:**
- Male:** \_\_\_\_\_ **Female:**
- Phone number from where call came:**
- NOTE:** Upon completion of the Initial Tampering Report Form, hand deliver the report to the Director.
13. **Person receiving the tampering information:**
- Name:**
- Phone Number:**
- Date:**
- Time:** \_\_\_\_\_

## **Work Section:**

### **DEPARTMENT CALL LIST**

If the Director is not available, contact the person listed No. 2 on the call list, or if not available, continue numerically down the contact list beginning with the person listed No. 3.

- |    |   |  |
|----|---|--|
| 1. | John W. Hasty<br>Director                                       | Home (804) 642-2020<br>Office (804) 662-9920<br>Pager (804) 351-6396                                     |
| 2. | Robert A. Nebiker<br>Deputy Director                            | Home (804) 379-3064<br>Office (804) 662-9966<br>Pager (804) 256-4520                                     |
| 3. | Faye Lemon<br>Director of Enforcement                           | Home (804) 730-3269<br>Office (804) 662-9954<br>VT (804) 278-0087<br>Pager (800) 351-7010<br>(Statewide) |
| 4. | Gary Anderson<br>Probation and Enforcement<br>Planning Director | Home (804) 725-5386<br>Office (804) 662-9933<br>VT (804) 278-0072<br>Pager (800) 597-9666                |

The following are provided for informational purposes only:

Scotti Russell Executive Director Board of Pharmacy	Home (804) 360-3551 Office (804) 662-9938
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Marcia Miller Executive Director Board of Dentistry	Home (804) 360-3639 Office (804) 662-9940
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Elizabeth Kirksey Executive Director Board of Funeral Directors & Embalmers, Nursing Home Administrators, & Audiology and Speech-Language Pathology	(804) 756-2067 Office (804) 662-9941
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Warren Koontz Executive Director	Home (804) 358-8878 Office (804) 662-9950
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## Board of Medicine

Karen Perrine  
Deputy Executive Director  
Board of Medicine

Home (804) 282-8624  
Office (804) 662-7006

Nancy Durrett  
Executive Director  
Board of Nursing

Home (804) 266-1825  
Office (804) 662-9945

Teresa Mullin  
Nursing Consultant  
Board of Nursing

Home (804) 231-3467  
Office (804) 662-9952

Jodi Power  
Nursing Consultant  
Board of Nursing

Home (804) 794-6281  
Office (804) 662-9951

Elizabeth Carter  
Executive Director  
Board of Optometry and  
Veterinary Medicine

Home (804) 458-3173  
Office (804) 662-9942

Evelyn Brown  
Executive Director  
Boards of Psychology,  
Sociology, and Professional  
Counselors

Home (804) 282-5175  
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## FIELD INVESTIGATION UNIT - NORTHERN VIRGINIA AREA

### REGIONAL INVESTIGATIVE SUPERVISOR

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PAGER: (703) 372-5602

### SENIOR INVESTIGATOR

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PAGER: (703) 702-9528

### SENIOR INVESTIGATOR

CHARLES F. JOHNSON  
HOME: (703) 658-5245  
CAR: (703) 819-6026  
VT: (804) 278-2215  
PAGER: (703) 372-2658

### SENIOR INSPECTOR

MARTA J. ISHMAEL  
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PAGER: (703) 701-7161

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PAGER: (703) 701-7193

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**FIELD INVESTIGATION UNIT - SOUTHWEST VIRGINIA AREA****REGIONAL INVESTIGATIVE SUPERVISOR**

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VT: (804) 278-0402  
PAGER: 800-289-2337 X 7531

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PAGER: 1-800-360-4915

**SENIOR INVESTIGATOR**

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### **REGIONAL INVESTIGATIVE SUPERVISOR**

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### **SENIOR INSPECTOR**

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VT: (804) 278-074  
PAGER: (804) 642-8117

## **FIELD INVESTIGATION UNIT - CENTRAL VIRGINIA AREA**

### **REGIONAL INVESTIGATIVE SUPERVISOR**

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PAGER: (804) 351-5886

### **SENIOR INVESTIGATOR**

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PAGER: (804) 351-7045

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### **SENIOR INVESTIGATOR**

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